IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

GLORIA STRAYHORN and JEREMY STRAYHORN,	)	
Plaintiffs,	)	
v.	)	**No. 11-2058-STA-cgc**
WYETH PHARMACEUTICALS, INC.; WYETH LLC; WYETH, INC.; PFIZER, INC.; SCHWARZ PHARMA, INC.; SCHWARZ PHARMA AG; UCB GmbH; ALAVEN PHARMACEUTICALS LLC; and ACTAVIS ELIZABETH LLC,	)	
Defendants.	)	

SARAH SPEED,	)	
Plaintiff,	)	
v.	)	**No. 11-2095-STA-cgc**
WYETH PHARMACEUTICALS, INC.; WYETH LLC; WYETH, INC.; PFIZER, INC.; SCHWARZ PHARMA, INC.; and WATSON LABORATORIES, INC.,	)	
Defendants.	)	

KATHLEEN SIMMONS,	)	
Plaintiff,	)	
v.	)	**No. 11-2083-STA-cgc**
WYETH PHARMACEUTICALS, INC.; WYETH LLC; WYETH, INC.; PFIZER,	)	

INC.; SCHWARZ PHARMA, INC.; ALAVEN PHARMACEUTICAL, LLC; and WATSON LABORATORIES, INC.,

Defendants.

GORDON and JUDITH WEAVER; SHENA JOHNSON; DEAN BROWN; GWENDOLYN RUFF; EMMA KETRON; LARRY HUDSON; ANNA ODOM; MARILYN MONCIER; THELMA DONALD; NETTER GRIGGS; ORVIELL RHODES; SELMA CARTER; and GERTIE KING,

Plaintiffs,

v. **No. 11-2134-STA-cgc**

WYETH PHARMACEUTICALS, INC., Individually and d/b/a ESI LEDERLE, INC.; WYETH HOLDINGS, INC.; PFIZER, INC.; SCHWARZ PHARMA, INC.; SCHWARZ PHARMA AG; ALAVEN PHARMACEUTICALS LLC; TEVA PHARMACEUTICALS USA, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; PLIVA, INC.; PLIVA, D.D.; BARR PHARMACEUTICALS LLC f/k/a BARR PHARMACEUTICALS, INC.; BARR LABORATORIES, INC.; DURAMED PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; RANBAXY PHARMACEUTICALS, INC.; MUTUAL PHARMACEUTICAL COMPANY, INC.; UNITED RESEARCH LABORATORIES, INC. a/k/a URL PHARMPRO, LLC d/b/a URL PHARMA; ACTAVIS ELIZABETH LLC as successor in interest of PUREPAC PHARMACEUTICALS, INC.; ACTAVIS GROUP HF; GENERICS BIDCO I LLC d/b/a QUALITEST

PHARMACEUTICALS; NORTHSTAR RX LLC; MCKESSON CORPORATION d/b/a NORTHSTAR RX LLC; THE HARVARD DRUG GROUP LLC d/b/a MAJOR PHARMACEUTICALS, INC.; and JOHN DOE DEFENDANTS,

Defendants.

IRVING EVANS and PHYLLIS EVANS,

Plaintiffs,

v. **No. 11-2060-STA-cgc**

WYETH PHARMACEUTICALS, INC.; WYETH LLC; WYETH, INC.; PFIZER, INC.; SCHWARZ PHARMA, INC.; ALAVEN PHARMACEUTICAL, LLC; PLIVA, INC.; BARR PHARMACEUTICALS, INC.; DURAMED PHARMACEUTICALS, INC.; and TEVA PHARMACEUTICALS USA, INC.,

Defendants.

MICHAEL BROOKS and KAREN BROOKS,

Plaintiffs,

v. **No. 11-2059-STA-cgc**

WYETH PHARMACEUTICALS, INC.; WYETH LLC; WYETH, INC.; PFIZER, INC.; SCHWARZ PHARMA, INC.; ALAVEN PHARMACEUTICALS LLC; PLIVA, INC.; BARR PHARMACEUTICALS, INC.; DURAMED PHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS

USA, INC.; and ACTAVIS ELIZABETH LLC,	)	
Defendants.	)	

ALTONA BAIN and WILLIAM BAIN; RUBY RUNIONS; DIANE MORPHIS and HOLLIS MORPHIS; BENNY ADAMS, Individually and as Legal Guardian of MARY ADAMS; CAROLYN CHURCHWELL; MARY RICHMOND; VELMA MAYBERRY and NATHAN MAYBERRY; CARRIE WILLIAMS and NATHANIEL WILLIAMS,	)	
Plaintiffs,	)	
v.	)	**No. 11-2145-STA-cgc**
WYETH PHARMACEUTICALS, INC., Individually and d/b/a ESI LEDERLE, INC.; WYETH LLC; WYETH, INC.; WYETH HOLDINGS, INC.; PFIZER, INC.; SCHWARZ PHARMA, INC.; SCHWARZ PHARMA AG; ALAVEN PHARMACEUTICALS LLC; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; PLIVA, INC.; PLIVA, D.D.; BARR PHARMACEUTICALS, INC.; BARR LABORATORIES, INC.; DURAMED PHARMACEUTICALS, INC.; ACTAVIS ELIZABETH LLC as successor in interest of PUREPAC PHARMACEUTICALS, INC.; ACTAVIS GROUP HF; NORTHSTAR RX LLC; MCKESSON CORPORATION d/b/a NORTHSTAR RX LLC; and JOHN DOE DEFENDANTS,	)	
Defendants.	)	

ORDER GRANTING GENERIC DEFENDANTS' MOTION TO DISMISS

Seven cases involving Defendant Wyeth LLC ("Wyeth") and other pharmaceutical companies identified later in this Order are currently pending before the Court. These cases revolve around Plaintiffs' injuries arising from their ingestion of the brand name drug Reglan or its generic version, metoclopramide. The Court will discuss the various Defendants in these cases below, but it will collectively refer to those manufacturing, distributing, marketing, selling, labeling, or designing Reglan as "the Brand Name Defendants" and those manufacturing, distributing, marketing, selling, labeling, or designing metoclopramide as "the Generic Defendants." Plaintiffs' Amended Complaint contains identical claims in each of these seven cases. Moreover, the parties' briefing of the Generic Defendants' Motions to Dismiss is identical in each case. Therefore, the Court finds that it can rely upon the documents in a single case as it evaluates the sufficiency of Plaintiffs' Amended Complaint. Accordingly, unless otherwise indicated, the Court will refer to the docket entry and page numbers in *Rhodes v. Wyeth*, No. 11-2134.

Before the Court is the Generic Defendants' Motion to Dismiss (D.E. # 173), filed on December 12, 2011. Plaintiffs filed a Response (D.E. # 183) on January 6, 2012. The Generic Defendants filed a Reply (D.E. # 192) on January 26, 2012. For the following reasons, the Generic Defendants' Motion is **GRANTED**.

BACKGROUND

Plaintiffs initially filed their Complaint (D.E. # 1) on February 22, 2011, alleging the following causes of action: fraud, intentional misrepresentation, and negligent misrepresentation; negligence; failure to warn; violation of the Tennessee Consumer Protection Act ("TCPA");

strict products liability; civil conspiracy; and punitive damages. However, the U.S. Supreme Court issued its opinion in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), on June 23, 2011, directly impacting both the contents of Plaintiffs' original Complaint and the Generic Defendants' then-pending Motions to Dismiss. Plaintiffs filed a Motion to Amend the Complaint in light of *Mensing*, and the Magistrate Judge granted the Motion. Accordingly, Plaintiffs filed their Amended Complaint in response to *Mensing*, which contains identical factual allegations and the same fourteen claims across all seven cases on November 28, 2011. (D.E. # 173.) The Generic Defendants then filed the Motions to Dismiss the Amended Complaint now pending before the Court.

The Court will now review the different parties in each case as named in the Amended Complaint and will discuss any parties which have been dismissed up to this point. Of course, the Court's ruling in this Order will extend only to those Generic Defendants which are still parties in each of the seven cases. In *Strayhorn v. Wyeth*, No. 11-2058, the Brand Name Defendants are Wyeth Pharmaceuticals, Inc., Wyeth LLC, Wyeth, Inc. (collectively "Wyeth"); Pfizer, Inc.; Schwarz Pharma, Inc. and Schwarz Pharma AG (collectively "Schwarz"); UCB GmbH; and Alaven Pharmaceuticals LLC ("Alaven"). The sole Generic Defendant in *Strayhorn* is Actavis Elizabeth LLC ("Actavis"). None of these Defendants have been dismissed. In *Brooks v. Wyeth*, No. 11-2059, Wyeth, Pfizer, Schwarz, and Alaven are the Brand Name Defendants. The Generic Defendants are PLIVA, Inc. ("PLIVA"); Barr Pharmaceuticals, Inc. ("Barr"); Duramed Pharmaceuticals, Inc. ("Duramed"); TEVA Pharmaceuticals USA, Inc. ("TEVA"); and Actavis. None of these Defendants have been dismissed.

In *Evans v. Wyeth*, No. 11-2060, the Brand Name Defendants are Wyeth, Pfizer, Schwarz, and Alaven, and the Generic Defendants are PLIVA, Barr, Duramed, and Teva. Plaintiffs dismissed their claims without prejudiced as to Brand Name Defendant Alaven on January 19, 2012. (*Evans*, No. 11-2060, D.E. # 105.) In *Simmons v. Wyeth*, No. 11-2083, the Brand Name Defendants are Wyeth, Pfizer, Schwarz, and Alaven, and the sole Generic Defendant is Watson Laboratories, Inc. ("Watson"). In *Speed v. Wyeth*, No. 11-2095, the Brand Name Defendants are Wyeth, Pfizer, and Schwarz; the sole Generic Defendant is Watson. No Defendants have been dismissed in either *Simmons* or *Speed*.

In *Rhodes v. Wyeth*, No. 11-2134, the Brand Name Defendants are Wyeth, Pfizer, Schwarz, and Alaven. The Generic Defendants are Teva, PLIVA, Barr, Duramed, Watson, Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy"), Mutual Pharmaceutical Company ("Mutual"), United Research Laboratories, Inc. ("URL"), Actavis, Generics Bidco I LLC ("Generics Bidco"), Northstar RX, LLC ("Northstar"), McKesson Corporation ("McKesson"), and The Harvard Drug Group. On June 16, 2011, Plaintiffs Gordon and Judith Weaver, Shena Johnson, Dean Brown, Emma Ketron, Larry Hudson, Anna Odom, Marilyn Moncier, Thelma Donald, Netter Griggs, Orviell Rhodes, Selma Carter, and Gertie King filed a Stipulation of Dismissal and dismissed all of their claims with prejudice against Generic Defendants Mutual and URL. (D.E. # 102.) However, the same subset of Plaintiffs also filed a Notice of Voluntary Dismissal with Prejudice as to Generic Defendants Mutual and URL on June 27, 2011, after their Stipulation of Dismissal.[1] (D.E. # 109.) On January 20, 2012, Plaintiffs Thelma Donald, Shena

[1] The Court expresses no opinion on this dual Stipulation of Dismissal and Notice of Voluntary Dismissal of the same Generic Defendants. After all, both Dismissals were with prejudice.

Johnson, and Emma Ketron and Brand Name Defendant Alaven filed a Stipulation of Dismissal dismissing all of these Plaintiffs' claims against Alaven without prejudice. (D.E. # 184.) Additionally, Plaintiff Emma Ketron and Brand Name Defendant Schwarz filed a Stipulation of Dismissal dismissing this Plaintiff's claims against Schwarz without prejudice. (D.E. # 185.)

Finally, in *Bain v. Wyeth*, No. 11-2145, the Brand Name Defendants are Wyeth, Pfizer, Schwarz, and Alaven. The Generic Defendants are Teva, PLIVA, Barr, Duramed, Watson, Ranbaxy, Mutual, URL, Actavis, Northstar, and McKesson. On February 23, 2012, Plaintiffs Altona and William Bain, Diane and Hollis Morphis, Carolyn Churchwell, Mary Richmond, Velma and Nathan Mayberry, and Carrie and Nathaniel Williams and Generic Defendant Northstar filed a Stipulation of Dismissal dismissing all of these Plaintiffs' claims against Northstar without prejudice. (*Bain*, No. 11-2145, D.E. # 166.)

The following facts are taken as true for purposes of this motion. Reglan is a prescription drug, and metoclopramide is its generic bioequivalent. (Am. Compl. ¶ 6.) Reglan and metoclopramide's product labeling recommends them for use as short-term therapies for symptomatic gastroesophageal reflux—heartburn—and acute and recurrent diabetic gastric stasis—bloating. (*Id.* ¶ 13.) The labels recommend therapy for up to twelve weeks in adults for heartburn, but they did not contain a durational limit for bloating. (*Id.* ¶ 14.) At no time have Reglan or metoclopramide been shown to be either efficacious or safe when used for long-term treatment. (*Id.* ¶ 15.)

Reglan and metoclopramide affect the brain's movement center, typically causing involuntary, repetitive movements. (*Id.* ¶ 7.) Overuse of Reglan and metoclopramide can result in extra-pyramidal symptoms including, but not limited to, tardive dyskinesia, dystonia, and

akathisia, Parkinsonism, and Reglan-induced tremors. (*Id.* ¶ 8.) Reglan and metoclopramide have also been associated with central nervous system disorders, depression with suicidal ideation, visual disturbances, and memory loss. (*Id.*) Tardive dyskinesia, dystonia, and akathisia are serious neurological movement disorders resulting in involuntary and uncontrollable movements of the head, neck, face, arms, or truck, as well as involuntary facial grimacing and tongue movements, including tongue thrusting, tongue chewing, extreme anxiety, and restlessness or other involuntary movements. (*Id.* ¶ 9.) These disorders have no known cure. (*Id.* ¶ 10.)

Patients using Reglan or metoclopramide for longer periods of time are at an "unreasonably dangerous increased risk of developing one or more severe and permanent neurological movement disorders, significantly and substantially greater than disclosed or suggested in the product labeling for the drug or in any other materials disseminated by the defendants to either the medical community or the public." (*Id.* ¶ 16.) Ordinary consumers would not appreciate the risk of developing one or more incurable severe neurological movement disorders when taking Reglan or metoclopramide as discussed above. (*Id.* ¶ 17.) Similarly, a prudent manufacturer would not market Reglan or metoclopramide due to the risk of severe and permanent neurological movement disorders and the availability of less dangerous alternative treatments. (*Id.* ¶ 18.)

Reglan is the reference listed drug ("RLD") in abbreviated new drug applications ("ANDAs") for generic versions of metoclopramide. (*Id.* ¶ 25.) ANDAs for new drugs must disclose to the Food and Drug Administration ("FDA") the drug's chemistry, pharmacology, and other matters, including its proposed labeling. (*Id.* ¶ 26.) For the FDA to approve a drug's

ANDA, its ANDA must include proposed labeling which discusses data and information about the risks and side effects of the drug, the drug's test results, results of animal studies, results of clinical studies, and the drug's bioavailability, all of which enable physicians or other foreseeable prescribers to use the drug safely. (*Id.*) Federal law requires the owner of an FDA-approved ANDA to ensure that the drug's labeling remains accurate and adequate, to conduct safety surveillance for adverse drug effects, and to periodically report to the FDA data related to the safety of the drug or the accuracy of its label. (*Id.* ¶ 27.) The FDA has not approved Reglan and metoclopramide for long-term or pediatric use. (*Id.* ¶ 28.)

The Amended Complaint contains three categories of claims: those against the Brand Name Defendants, the Generic Defendants, and all Defendants. Accordingly, the Court will set forth those factual allegations pertaining only to claims against all Defendants or only the Generic Defendants, as the Brand Name Defendants have filed Answers in all seven cases and are not parties to these Motions to Dismiss. Plaintiffs allege that all Defendants knew or should have known that most physicians did not know or fully appreciate the seriousness of the risks associated with Reglan or metoclopramide. (*Id.* ¶ 31.) Moreover, all Defendants knew that physicians commonly prescribed the drug for inappropriate long term and pediatric use, as well as short term use for certain adults. (*Id.*) Thus, all Defendants "should have known that the *Physician's Desk Reference* monograph for Reglan and the package inserts for Reglan and metoclopramide were deficient, inaccurate, [or] false and misleading in communicating [information] to the medical community in general, to physicians, or to the public." (*Id.*) Plaintiffs allege that all Defendants "failed to adequately inform physicians and misled [them] about the risks associated with their metoclopramide drug products." (*Id.* ¶ 33.)

Plaintiffs aver that all Defendants "knew or . . . should have known that the labeling for Reglan and generic metoclopramide substantially understated the frequency of acute and long term side effects of the drug." (*Id.* ¶ 35.) Thus, all Defendants "failed to use reasonable care to ascertain or communicate to physicians or to the public information that would constitute adequate and effective warnings." (*Id.*) Additionally, all Defendants knew through their own studies or "publicly available published literature" that doctors commonly prescribed metoclopramide for longer than twelve weeks, for pediatric use, or in other unsafe situations. (*Id.* ¶ 37.) All Defendants also knew that their "individual and collective failure to communicate [information] to the medical community . . . about the risks of long term and other metoclopramide therapy would . . . likely . . . result in serious injury." (*Id.* ¶ 38.) Defendants failed to adequately communicate this information and failed to exercise due care to ensure that their warnings were effectively communicated; Defendants also had a duty to adequately communicate these warnings. (*Id.* ¶ 38-39.) All Defendants breached this duty in a number of ways. (*Id.* ¶ 40a-40g.) Moreover, all Defendants "failed to make reasonable efforts to ensure that accurate and adequate information regarding metoclopramide was provided to the medical community" and consumers or "to inform the FDA of the need for changes to its label." (*Id.* ¶ 48.)

The Amended Complaint also contains facts related directly to the Generic Defendants' "failure to communicate adequate warnings." (*Id.* at 22.) The Food, Drug, and Cosmetic Act ("FDCA") requires a generic drug's ANDA to include proposed labeling identical to the brand-name RLD in all material respects. (*Id.* ¶ 43.) Accordingly, the Generic Defendants submitted ANDAs for metoclopramide containing labels identical to the FDA-approved label for Reglan.

(*Id.* ¶ 44.) The Generic Defendants had several duties, including the duty to ensure that their metoclopramide labels contained accurate information regarding the drug's intended uses and other common uses, to conduct post-market safety surveillance, to review adverse drug event information, to make timely revisions to the labels after revisions were made to the RLD label, and to ensure that information regarding the drug's safety was communicated to the medical community and consumers. (*Id.* ¶ 46.) The Generic Defendants were also required to effectively communicate the labels and their warnings to physicians and patients. (*Id.*) Plaintiffs allege that the Generic Defendants violated these duties in a number of ways, including by failing to "actually and effectively communicate" the labels and their warnings, to properly evaluate and understand how physicians and patients were using metoclopramide, to properly research, test, and market metoclopramide, to periodically review all medical literature, to independently monitor metoclopramide sales to alert them that it was widely overprescribed due to inadequate warnings, and to engage in marketing practices designed to minimize the risks associated with metoclopramide. (*Id.* ¶ 47a-47f.)

On February 26, 2009, the FDA exercised its new agency powers and ordered all Defendants to add a black box warning to Reglan's label. (*Id.* ¶ 49.) This new warning—the strongest available under FDA regulations—highlighted the "high risk of tardive dyskinesia with long term, high dose, or pediatric use of metoclopramide, even after the drugs are no longer taken." (*Id.*) The FDA also required all Defendants to create a Risk Evaluation and Mitigation Strategy to ensure that they communicated information regarding the risks associated with metoclopramide directly to the consumers of the drug. (*Id.* ¶ 50.) Plaintiffs allege that prior to 2007, when the FDA did not have the authority to demand such action from drug companies, all

Defendants knew that the metoclopramide and Reglan warnings were insufficient, but they "did nothing to communicate accurate information to individuals prescribing and consuming metoclopramide." (*Id.* ¶ 51.) Plaintiffs aver that they were injured due to overexposure to Reglan or metoclopramide caused by all Defendants' failure "to monitor the safety of their drug products, to provide accurate and complete information to the FDA, to use reasonable means to correct inaccuracies appearing in their labels, to communicate to the medical community, physicians, Plaintiffs' physicians, Plaintiffs[,] and other foreseeable users of the drug adequate warnings about risks associated with common and foreseeable uses of their metoclopramide products." (*Id.* ¶ 54.) "Concurrently, Plaintiffs' injuries came about as a foreseeable and proximate result of [all D]efendants' inaccurate, misleading, materially incomplete, and otherwise false information concerning the potential effects of exposure to the drug substance metoclopramide and the ingestion of metoclopramide products manufactured and sold by [all] Defendants." (*Id.*)

Plaintiffs' Amended Complaint contains fourteen causes of action: strict liability against all Defendants; strict liability due to a design defect against all Defendants; negligence against all Defendants, with specific allegations against the Generic Defendants only; negligence per se against all Defendants, with specific allegations of misbranding against the Generic Defendants only; fraud, misrepresentation, and suppression against all Defendants, with specific allegations against Wyeth, Schwarz, and other Brand Name Defendants; constructive fraud against all Defendants; breach of express and implied warranties against all Defendants; unfair and deceptive trade practices in violation of the TCPA against all Defendants; unjust enrichment against all Defendants; conscious or negligent misrepresentation involving physical harm against

the Brand Name Defendants only, with specific allegations against Wyeth, Schwarz, and Alaven; civil conspiracy against all Defendants; loss of consortium against all Defendants; wrongful death against all Defendants; survival actions against all Defendants; and punitive damages against all Defendants for their reckless, fraudulent, intentional, or malicious actions. (*Id.* at 27-64.) The Court counts a total of fifteen claims, fourteen of which are asserted against both the Generic Defendants and the Brand Name Defendants. The only claim not asserted against the Generic Defendants is Plaintiffs' conscious or negligent misrepresentation claim. Therefore, this Order will address the remaining fourteen claims only.[2]

STANDARD OF REVIEW

A defendant may move to dismiss a claim for "failure to state a claim upon which relief can be granted" under Rule 12(b)(6). When considering a Rule 12(b)(6) motion, the Court must treat all of the well-pled factual allegations of the complaint as true, construe those allegations in the light most favorable to the non-moving party, and draw all reasonable inferences in favor of the plaintiff.[3] However, legal conclusions "masquerading as factual allegations" or unwarranted factual inferences including "conclusory allegations" need not be accepted as true.[4] To avoid dismissal under Rule 12(b)(6), "the complaint must contain either direct or inferential allegations" with respect to all material elements of the claim.[5]

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[2] Although Plaintiffs have not filed their Short Form Complaints in the individual cases, the Court finds that the broad factual allegations in the Amended Complaint are sufficient to decide the issues presented in the Generic Defendants' Motion.

[3] *Jones v. City of Cincinnati*, 521 F.3d 555, 559 (6th Cir. 2007).

[4] *Id.*

[5] *Eidson v. State of Tenn. Dep't of Children's Servs.*, 510 F.3d 631, 634 (6th Cir. 2007).

Under Rule 8 of the Federal Rules of Civil Procedure, a complaint need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief[.]"[6] Although this standard does not require "detailed factual allegations," it does require more than "labels and conclusions" or "a formulaic recitation of the elements of a cause of action."[7] To survive a motion to dismiss, the plaintiff must allege facts that, if accepted as true, are sufficient "to raise a right to relief above the speculative level" and to "state a claim to relief that is plausible on its face."[8] "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."[9]

ANALYSIS

The Order will be composed of three main parts. First, the Court will examine *Mensing* and its progeny to determine the scope of *Mensing*'s holding and whether the 2007 FDA amendments would alter the Court's application of *Mensing*. Second, the Court will evaluate whether Tennessee's products liability law is sufficiently similar to that of Louisiana and Minnesota to render *Mensing* applicable. Third, the Court will determine whether Plaintiffs' Amended Complaint can escape *Mensing*'s sweeping preemption holding by examining each of Plaintiffs' arguments.

Mensing and its Sixth Circuit progeny

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[6] Fed. R. Civ. P. 8(a)(2).

[7] *Ashcroft v. Iqbal*, 556 U.S. 662, 684-85 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also Hensley Mfg. v. ProPride, Inc.*, 579 F.3d 603, 609 (6th Cir. 2009).

[8] *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 570.

[9] *Iqbal*, 556 U.S. at 678.

Mensing involved the same drug—metoclopramide—made by generic sellers and manufactures similar or identical to those in the case at bar.[10] As here, the generic manufacturers argued that "federal statutes and FDA regulations required them to use the same safety and efficacy labeling as their brand-name counterparts. This means, they argued, that it was impossible to simultaneously comply with both federal law and any state tort-law duty that required them to use a different label."[11] In its decision, the Supreme Court relied on pre-2007 FDA statutes and regulations and "express[ed] no view on the impact of the 2007 Act."[12] The Court will discuss this regulatory framework before turning to the Supreme Court's preemption discussion.

These regulations permitted generic versions of brand name drugs to gain FDA approval "simply by showing equivalence to a reference listed drug that has already been approved by the FDA."[13] In contrast, brand name drugs have a lengthy, expensive authorization process.[14] Generic drugs are "equivalent" when they have the same labeling approved for the brand name drug and their active ingredients, safety, and efficacy are a copy of the RLD.[15] Thus, "brand

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[10] *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011).

[11] *Id.* at 2573.

[12] *Id.* at 2574 n.1. The Court has reviewed the 2007 Amendments to the FDCA, and the statutes and regulations cited in *Mensing* appear to be unaltered. Moreover, Plaintiffs have not argued that the 2007 FDCA Amendments would distinguish *Mensing* from the case at bar. Accordingly, the Court finds that the 2007 FDCA Amendments do not remove this case from *Mensing*'s scope.

[13] *Id.* at 2574.

[14] *Id.*

[15] *Id.* (citing 21 U.S.C. 355(j)(2)(A)(v); 21 C.F.R. § 314.3(b) (2006)).

name and generic drug manufacturers have different federal drug labeling duties. A brand name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label [while a] manufacturer seeking generic drug approval . . . is responsible for ensuring that its warning label is the same as the brand name's."[16] Deferring to the FDA's interpretation of its regulations, the Supreme Court noted that the FDA always requires the warnings labels of a brand name drug and its generic copy to be the same—"thus, generic drug manufacturers have an ongoing federal duty of 'sameness.'"[17]

The FDA regulations also contain a "changes-being-effected" ("CBE") process which permits manufacturers to change their labels when necessary.[18] Under the CBE process, labels can be strengthened or can add instructions about dosage or drug administration which are intended to make the drug safer to use.[19] However, the FDA does not permit generic manufacturers to change their labels unilaterally through the CBE process; generic manufacturers can only use the CBE process to change generic drugs' labels "when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions."[20] Otherwise, unilateral generic label changes would violate the sameness

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[16] *Id.*

[17] *Id.* at 2574-75. The sameness requirement arises because the listed drug product—the brand name drug—is the basis for the generic drug's approval. *Id.* at 2575 (citing 57 Fed. Reg. 17961 (1992)).

[18] *Id.* at 2575.

[19] *Id.*

[20] *Id.*

requirement imposed by other FDA regulations.[21] Thus, the Supreme Court held that the CBE process was not open to the generic manufacturers for the sort of change required by state law.[22] Congress does not appear to have modified these portions of the FDA regulations when it enacted the Food and Drug Administration Amendments Act of 2007 ("the 2007 Act"); therefore, the 2007 Act does not remove *Mensing* from application here.

Additionally, the Supreme Court discussed the use of "Dear Doctor" letters to send additional warnings to prescribing physicians and other healthcare professionals.[23] Again deferring to the FDA's interpretation of its regulations, the Supreme Court noted that Dear Doctor letters qualify as labeling; thus, any letters sent by manufacturers must be "consistent with and not contrary to the drug's approved labeling."[24] Thus, generic manufacturers cannot send Dear Doctor letters containing substantial new warning information because that information would not be consistent with the drug's approved labeling.[25] Moreover, if generic manufacturers sent the letters and brand name manufacturers did not, an inaccurate therapeutic difference would be implied, which could be impermissibly misleading.[26] Thus, federal law did

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21 *Id.*

22 *Id.* at 2575-76.

23 *Id.* at 2576.

24 *Id.* (internal punctuation omitted) (quoting 21 C.F.R. § 201.100(d)(1)).

25 *Id.*

26 *Id.*

not allow the generic manufacturers to issue additional warnings through Dear Doctor letters or other doctor or patient communications.[27]

The Supreme Court aptly summarized the labeling regulations as follows:

> State tort law places a duty directly on all drug manufacturers to adequately and safely label their products. Taking [Plaintiffs'] allegations as true, this duty required the [generic m]anufacturers to use a different, stronger label than the label they actually used. Federal drug regulations, as interpreted by the FDA, prevented the [generic m]anufacturers from independently changing their generic drugs' safety labels. But . . . federal law also required the [generic m]anufacturers to ask for FDA assistance in convincing the brand-name manufacturer[s] to adopt[] a stronger label, so that all corresponding generic drug manufacturers could do so as well.[28]

Because the Supreme Court ultimately found preemption under the assumption that the generic manufacturers had a duty to approach the FDA for assistance, it did not resolve whether such a duty actually exists.[29] The Court will adopt a similar assumption and need not resolve whether the Generic Defendants had such a duty.

The Supreme Court held that all of the plaintiffs' state tort-law claims for failure to warn were preempted due to impossibility preemption. Impossibility preemption is a type of implied conflict preemption which occurs when "state and federal law conflict [and] it is impossible for a private party to comply with both state and federal requirements."[30] The Supreme Court noted that any independent change to the generic metoclopramide labels would have violated federal

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[27] *Id.*

[28] *Id.* at 2577.

[29] *Id.*

[30] *Id.* (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).

law, but those independent changes were necessary due to state tort law.[31] Nor did the assumed "federal duty to ask the FDA for help in strengthening the corresponding brand name label" preclude preemption: "[s]tate law demanded a safer label; it did not instruct the [generic m]anufacturers to communicate with the FDA about the possibility of a safer label."[32] Thus, the Supreme Court articulated the following holding regarding preemption:

> [W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes. Here, state law imposed a duty on the [generic m]anufacturers to take a certain action, and federal law barred them from taking that action. The only action the [generic m]anufacturers could independently take—asking for the FDA's help—is not a matter of state-law concern. [Plaintiffs'] tort claims are pre-empted.[33]

Although the Supreme Court held that state tort-law claims against brand name manufacturers under the same regulations were not preempted in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), the Supreme Court distinguished *Levine* based on the type of drug taken by the plaintiffs—generic versus brand name—and the type of manufacturer—again, generic versus brand name.[34] Thus, although the dissent aptly noted that "whether a consumer harmed by inadequate warnings can obtain relief turns solely on the happenstance of whether [his or] her pharmacist filled [his or] her prescription with a brand-name or generic drug," the Supreme

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31 *Id.* at 2578.

32 *Id.*

33 *Id.* at 2581.

34 *Id.*

Court's holding in *Mensing* is clear: state law failure to warn claims against generic defendants related to the contents of the label are preempted.[35]

The Court will now summarize Sixth Circuit cases discussing *Mensing*. The Sixth Circuit has issued one opinion discussing *Mensing*. In *Smith v. Wyeth*, the plaintiffs sued brand name manufacturers of Reglan and generic manufacturers of metoclopramide although they were injured by only taking metoclopramide; they did not take Reglan.[36] The Sixth Circuit dealt with the plaintiffs' failure to warn claims against the generic manufacturers in one paragraph:

> On appeal, the plaintiffs contend that the district court erred in concluding that their state-law failure-to-warn claims against the generic defendants were preempted by federal law. . . . Their arguments must fail. . . . The Supreme Court held unequivocally . . . that federal law preempts state laws that impose on generic drug manufacturers the duty to change a drug's label, thus barring the plaintiffs' state-law tort claims. The plain language of the [*Mensing*] decision compels the same result here.[37]

Although the Sixth Circuit did not discuss whether Kentucky's products liability law was similar to that of the Louisiana and Minnesota laws discussed in *Mensing*, it applied *Mensing*'s broad preemption holding and affirmed the district court's preemption of the plaintiffs' state law failure to warn claims against the generic manufacturers.[38]

The only district courts in the Sixth Circuit to cite *Mensing* have applied it in a similar fashion. First, in *Fulgenzi v. PLIVA, Inc.*, the court faced a motion to dismiss the plaintiff's claims for injuries suffered by taking metoclopramide under Ohio common law for various torts,

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35 *Id.* at 2583 (Sotomayor, J., dissenting).

36 *Smith v. Wyeth*, 657 F.3d 420, 422 (6th Cir. 2011).

37 *Id.* at 423.

38 *Id.*

including strict liability, breach of express and implied warranty, fraud, misrepresentation, negligence, and Ohio statutory products liability law for defective manufacturing, design defects, failure to warn, and non-conformance with representations.[39] The court noted that the plaintiff's common law tort claims were abrogated by Ohio's statutory products liability law, and it also found that the plaintiff did not sufficiently plead her defective design and manufacturing claims.[40] The court also found that the plaintiff did not have standing to assert a violation of FDA regulations regarding the generic manufacturer's failure to conform its warning label to that of the name brand manufacturers.[41]

Finally, the court found that *Mensing* preempted all of the plaintiff's remaining claims because the claims were, "at the core, failure-to-warn claims."[42] Indeed, the court noted that "a review of the allegations supporting each claim in the Second Amended Complaint reveals that all of the claims, including those otherwise abrogated by the [Ohio products liability law] hinge on the warnings the drug manufacturers gave, or from [the p]laintiff's perspective, failed to give. Because the essence of these claims is that PLIVA and others marketed and sold a product as

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[39] *Fulgenzi v. PLIVA, Inc.*, No. 5:09CV1767, 2012 WL 1110009, at *5 (N.D. Ohio Mar. 31, 2012) (publication forthcoming).

[40] *Id.* at *6.

[41] *Id.* at *7.

[42] *Id.* The court did not find the plaintiff's argument that the generic manufacturers could have chosen to stop selling metoclopramide persuasive: "[w]hile such an argument was embraced by the Eighth Circuit in [its *Mensing* decision], the Supreme Court did not find the argument persuasive as it reversed the Eighth Circuit and dismissed all of the claims as preempted under federal law." *Id.* at *7 n.5.

safe when they should have advised doctors and patients of the risk created by long-term use of the medication, the case comes down to the warning."[43]

Second, in *In re Darvocet, Darvon and Propoxyphene Products Liability Litigation*, a Multi-District Litigation collection of cases in the Eastern District of Kentucky, the court applied *Mensing*'s preemption holding to claims against generic drug manufacturers who made drugs other than metoclopramide.[44] The court was not persuaded by plaintiffs' repackaging of their claims from failure to warn to "failure to withdraw [their products from the market: t]he *Mensing* plaintiffs made the same argument, without success, in their petition for rehearing."[45] The court recognized the broad scope of *Mensing*'s preemption effect, and it held that all failure to warn claims—even those styled as different claims, such as negligence per se, fraud, misrepresentation, and consumer-production claims—were preempted because they all "relate[d] to the sufficiency of the warnings on propoxyphene products."[46] Furthermore, the plaintiffs' claims for the generic defendants' failure to comply with the FDA's regulations were preempted pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), which recognized that the FDA is the sole entity with the power to enforce FDA regulations and that "state-law claims 'based on failure to properly communicate with the FDA' were preempted."[47]

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[43] *Id.* at *7.

[44] *In re Darvocet, Darvon & Propoxyphene Prods. Liab. Litig.*, No. 2:11-md-2226-DCR, MDL No. 2226, 2012 WL 718618 (E.D. Ky. Mar. 5, 2012) [hereinafter *Darvocet MDL*].

[45] *Id.* at *3.

[46] *Id.* at *5.

[47] *Id.* at *6 (quotation omitted).

Additionally, the same court was not persuaded by the First Circuit's *Bartlett* decision, cited here by Plaintiffs as supplemental authority.[48] The court rejected *Bartlett* for two reasons. First, the First Circuit adopted the "failure to withdraw" argument previously rejected by it and other courts, including the Supreme Court in the *Mensing* plaintiffs' petition for rehearing, the Eighth Circuit on remand in *Mensing*, and the Sixth Circuit in *Smith*.[49] Second, the First Circuit offered little explanation for accepting the failure to withdraw theory, noting simply that the *Mensing* opinion had not specifically addressed design-defect claims.[50]

In addition to their arguments regarding preemption, which the Court will discuss below, the parties have provided supplemental authority addressing the preemption issue. The Generic Defendants presented thirteen cases from a variety of jurisdictions which noted the broad sweep of *Mensing*'s holding.[51] In response, Plaintiffs produced two cases, one from the California Superior Court, in which the court held that all of plaintiff's claims other than their failure to warn claims were not preempted, and the other from the First Circuit,[52] in which the court refused to apply *Mensing*'s preemption exception to design defect claims in the face of *Levine*'s general no-preemption rule.[53] In reply, the Generic Defendants presented an additional nine

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[48] *Darvocet MDL*, No. 2:11-md-2226-DCR, MDL No. 2226, 2012 WL 2457825, at *1 (E.D. Ky. June 22, 2012).

[49] *Id.*

[50] *Id.*

[51] (Generic Defs.' Supp. Authority, D.E. # 216, at 1-5.)

[52] *Bartlett v. Mutual Pharm. Co., Inc.*, 678 F.3d 30 (1st Cir. 2012).

[53] (Pls.' Supp. Authority, D.E. # 219, at 2.)

cases from across the country applying *Mensing* and finding preemption,[54] and they filed additional supplemental authority of eight other cases applying *Mensing* and finding preemption.[55]

The Court has reviewed this authority, and it finds that the weight of it favors application of *Mensing*'s impossibility preemption to this case's failure to warn claims. Plaintiffs' reliance on a California Superior Court decision does not persuade the Court: not only is the California decision in the vast minority of the courts to look at the issue, the Court does not find the California court's reasoning compelling. Moreover, *Bartlett* involved a drug which the plaintiff alleged was unreasonably dangerous; here, the crux of Plaintiffs' unreasonably dangerous argument is that metoclopramide is unreasonably dangerous when taken for more than twelve weeks. Thus, *Bartlett* does not squarely apply, and in any case, it is non-binding authority.

After reviewing these cases and others, the Court has found several principles governing the law applicable to this case. First, *Mensing* means what it says: all failure to warn claims against generic drug manufacturers are preempted if generic manufacturers cannot independently alter their warning labels. Second, any claims in which plaintiffs attempt to enforce FDA regulations are preempted by *Buckman*, as the FDA is the only entity with the power to pursue enforcement actions for violation of the FDCA.[56] Third, plaintiffs' argument that generic manufacturers face liability because they did not remove their products from the market has not

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[54] (Generic Defs.' Additional Supp. Authority, D.E. # 221, at 1-5.)

[55] (Generic Defs.' Third Supp. Authority, D.E. # 222, at 1-3.)

[56] *See Buckman*, 531 U.S. at 348.

been adopted by the Supreme Court or other Circuits. Accordingly, the Court will now turn to Tennessee's products liability law to determine whether *Mensing* squarely applies to this case.

Tennessee Products Liability Law

The Court will discuss the products liability law at issue in *Mensing* before turning to the Tennessee Products Liability Act ("TPLA"). In *Mensing*, the Supreme Court noted that "[i]t is undisputed that Minnesota and Louisiana require a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe."[57] Under Minnesota law, "where the manufacturer . . . of a product has actual or constructive knowledge of danger to users, the . . . manufacturer has a duty to give warning of such dangers."[58] Similarly, under Louisiana law, "a manufacturer's duty to warn includes a duty to provide adequate instructions for [the] safe use of a product."[59] Thus, the Supreme Court found that in both states, "a duty to warn falls specifically on the manufacturer."[60]

The TPLA governs products liability actions in Tennessee[61] and defines "product liability action[s]" as "all actions brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packing, or labeling of any

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[57] *Mensing*, 131 S. Ct. at 2573.

[58] *Id.* (quoting *Frey v. Montgomery Ward & Co.*, 258 N.W.2d 782, 788 (Minn. 1977)).

[59] *Id.* (quoting *Stahl v. Novartis Pharm. Corp.*, 283 F.3d 254, 269-70 (5th Cir. 2002).

[60] *Id.*

[61] *Lee v. Metro. Gov't of Nashville & Davidson Cnty.*, 596 F. Supp. 2d 1101, 1126-27 (M.D. Tenn. 2009).

product."[62] The TPLA also encompasses several different theories of products liability: "strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or under any other substantive legal theory in tort or contract whatsoever."[63]

In Tennessee, products are defective when they are in a condition which renders them "unsafe for normal or anticipatable handling and consumption."[64] However, products can be unreasonably dangerous in one of two ways. First, the product can be "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics."[65] Second, "because of its dangerous condition[, the product] would not be put on the market by a reasonably prudent manufacturer or seller, assuming that the manufacturer or seller knew of its dangerous condition."[66] Moreover, the learned intermediary rule shields manufacturers from liability if they adequately warn physicians of drugs' risks; on the other hand, if manufacturers do not properly warn physicians, they can be held liable for a doctor's failure to adequately warn a patient.[67]

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62 Tenn. Code Ann. § 29-28-102(6).

63 *Id.*

64 *Id.* § 29-28-102(2).

65 *Id.* § 29-28-102(8).

66 *Id.*

67 *See King v. Danek Med., Inc.*, 37 S.W.3d 429, 452 (Tenn. Ct. App. 2000).

Applying the TPLA's definitions, the Tennessee Supreme Court has noted that manufacturers of prescription drugs "have a duty to market and distribute their products in a way that minimizes the risk of danger. They may discharge their duty by distributing the drugs with proper directions and adequate warnings to those who foreseeably could be injured by the use of their products."[68] Warnings are reasonable when they both convey a fair indication of the dangers involved in taking a prescription drug and warn with the degree of intensity required by the nature of the risk.[69] Thus, it appears that the TPLA and Tennessee courts' interpretation of its provisions align with the Minnesota and Louisiana laws held to be preempted in *Mensing*, and the fact that Tennessee law was not at issue in *Mensing* does not remove this case from *Mensing*'s scope. Furthermore, district courts in the Sixth Circuit have applied *Mensing*'s holding to the products liability law of both Kentucky and Ohio in *Darvocet MDL* and *Fulgenzi*, and the Sixth Circuit applied *Mensing* to Kentucky law in *Smith*. Thus, other courts in this Circuit have applied *Mensing*'s holding to cases arising under other states' laws, and the Court's application of *Mensing* to Tennessee law would not be the first application of *Mensing*'s principles to states other than Minnesota and Louisiana. The Court now turns to the merits of the Generic Defendants' Motion.

Generic Defendants' Motion to Dismiss

The Court will group Plaintiffs' fourteen claims into several categories: abandoned claims, failure to warn, failure to conform, failure to remove products from the market, unjust enrichment and civil conspiracy, and derivative claims. It will address each grouping in turn.

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[68] *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428 (Tenn. 1994).

[69] *Id.* at 429.

Abandoned Claims

In their Motion, the Generic Defendants move for dismissal of all of Plaintiffs' claims against them.[70] Although Plaintiffs filed a thorough Response opposing the majority of the Generic Defendants' arguments, the Generic Defendants' Reply notes that Plaintiffs did not oppose dismissal of several claims: negligence per se, unfair and deceptive trade practices/conspiracy, unjust enrichment, and conscious or negligent misrepresentation involving physical harm.[71] Although the Court finds that Plaintiffs did oppose dismissal of their negligence per se claim by opposing dismissal of their negligence claim and conscious or negligent misrepresentation involving physical harm claim by opposing dismissal of their negligent misrepresentation claim, the Court also finds that Plaintiffs did not respond to the Generic Defendants' arguments regarding their unfair and deceptive trade practices/conspiracy claim or their unjust enrichment claim.

Thus, it appears to the Court that Plaintiffs have abandoned these claims in the face of the Generic Defendants' meritorious arguments. District courts in this Circuit routinely grant dismissal of claims a plaintiff fails to support or address in a response to a motion.[72] Moreover,

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[70] (*See generally* Generic Defs.' Mot., D.E. # 173-1, at 18-19.)

[71] (Generic Defs.' Reply, D.E. # 192, at 3 n.2.)

[72] *See Burress v. City of Franklin, Tenn.*, 809 F. Supp. 2d 795, 809 (M.D. Tenn. 2011); *Anglers of the Au Sable v. U.S. Forest Serv.*, 565 F. Supp. 2d 812, 839 (E.D. Mich. 2008); *Dage v. Time Warner Cable*, 395 F. Supp. 2d 668, 679 (S.D. Ohio 2005); *Kattar v. Three Rivers Area Hosp. Auth.*, 52 F. Supp. 2d 789, 798 n.7 (W.D. Mich. 1999). *See also Clark v. City of Dublin*, No. 05-3186, 2006 WL 1133577, at *3 (6th Cir. Apr. 27, 2006) (where the appellant did not properly respond to the arguments asserted against his ADEA and ADA claims by the appellees in their motion for summary judgment, the appellant had abandoned his ADEA and ADA claims); *Conner v. Hardee's Food Sys.*, No. 01-5679, 2003 WL 932432, at *4 (6th Cir. Mar. 6, 2003) (finding that the plaintiffs abandoned their claim "[b]ecause Plaintiffs failed to brief the issue before the district court"); *Hazelwood v. Tenn. Dept. of Safety*, No. 3:05-cv-356,

this Court has previously dismissed unsupported claims.[73] Therefore, the Court finds that Plaintiffs have abandoned their unfair and deceptive trade practices/conspiracy and unjust enrichment claims.[74] As such, the Generic Defendants' Motion is **GRANTED** in that regard.

Failure to Warn Claims

In their Motion, the Generic Defendants rest on *Mensing*, contend that all of Plaintiffs' variously labeled claims are really failure to warn claims in disguise, and assert that all of the claims are preempted just as those in *Mensing*.[75] And they cite authority from district courts across the country holding similarly.[76] The Generic Defendants interpret Plaintiffs' "failure to communicate warnings" claims as allegations that the Generic Defendants breached a duty to send Dear Doctor letters to physicians "informing them of labeling changes or, as some allegations suggest, of 'adequate clinically relevant information and data and warnings.'"[77] The Generic Defendants cite to *Mensing* and *Smith* and argue that these failure to communicate theories should be dismissed.[78]

2008 WL 3200720, at *8 (E.D. Tenn. Aug. 5, 2008).

[73] *See, e.g.*, *McNeil v. Sonoco Prods. Co.*, No. 10-2411-STA, 2012 WL 1038767, at *8 (W.D. Tenn. Mar. 27, 2012).

[74] Even if Plaintiffs did not abandon these claims, the Court finds that they are, at their core, failure to warn claims subject to preemption as discussed in *Mensing*.

[75] (Generic Defs.' Mot., D.E. # 173-1, at 6, 16-17.)

[76] (*Id.* at 7-9.)

[77] (*Id.* at 9.)

[78] (*Id.* at 10-12.) Alternatively, the Generic Defendants argue that the TPLA does not recognize a claim for "failure to communicate." (*Id.* at 13.) The Generic Defendants interpret the TPLA as not permitting Plaintiffs' new "failure to communicate" theory, and they cite to a case from the Middle District of Tennessee as proof that "this Court has thrown out

The Generic Defendants also appear to argue that the TPLA requires an inadequate warning to be a necessary element of any claim against a pharmaceutical manufacturer.[79] They lift the phrase "to the extent the plaintiff has a viable strict liability claim, it would arise under a failure-to-warn theory"[80] from the Middle District's order and submit that "[p]harmaceutical products cannot be defective or unreasonably dangerous unless accompanied by inadequate warnings."[81] But the TPLA's text does not support this assertion. Indeed, the TPLA defines a "product liability action" as arising from damage caused by "manufacture, construction, design, formula, marketing, packaging, or labeling of any product."[82] Thus, a manufacturer can be liable for damage arising from any number of negligent or innocent actions, not just labeling. The Court is not persuaded by the Generic Defendants' arguments to the contrary. Accordingly, Plaintiffs' assorted theories of liability will survive the Generic Defendants' Motion only if their claims are not, "at their core," failure to warn claims.

In response, Plaintiffs argue that "the *Mensing* [c]ourt's interpretation of the requirements of other states' laws is inapplicable to the present situation as Tennessee law differs substantially

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novel causes of action . . . not listed in the TPLA." (*Id.*) But the TPLA's text does not support this assertion: § 29-28-102(6) does provide a list of recognized products liability actions, but the TPLA also provides that its coverage "is not limited to" the actions in the list. Tenn. Code Ann. § 29-28-102(6). Accordingly, the Court is unpersuaded by this argument.

[79] (Generic Defs.' Mot., D.E. # 173-1, at 15-16.)

[80] *Rodriguez v. Stryker Corp.*, No. 2:08-0124, 2011 WL 31462, at *6 (M.D. Tenn. Jan. 5, 2011).

[81] (Generic Defs.' Mot., D.E. # 173-1, at 16.)

[82] Tenn. Code Ann. § 29-28-102(6).

from the requirements of state law considered in *Mensing*."[83] Unsurprisingly, Plaintiffs interpret *Mensing* narrowly and argue that Tennessee law does not require a generic drug manufacturer to change its label.[84] Plaintiffs also rely on the fact that federal law required the Generic Defendants to monitor the safety of their drug products and to incorporate warnings contained in the FDA-approved RLD labels.[85] Thus, they argue that the Generic Defendants cannot invoke preemption because they were not in compliance with federal law.[86]

After minimizing *Mensing*'s holding,[87] Plaintiffs present a thorough analysis of several Supreme Court preemption cases involving products' labeling and submit that these cases, involving tobacco litigation and pesticides produced by Dow, preserve the majority of Plaintiffs' claims after *Mensing*'s application.[88] Plaintiffs also point to the FDA's Dear Doctor letter regulations and argue that the Generic Defendants' failed to provide information about metoclopramide's risk through Dear Doctor letters, training programs for healthcare practitioners or patients, continuing healthcare education, prominent professional or public notifications, or

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[83] (Pls.' Resp., D.E. # 183, at 2.) The Court examined the Minnesota and Louisiana law discussed in *Mensing* above and found that Tennessee law did not differ enough to distinguish *Mensing*. Thus, this portion of Plaintiffs' argument is without merit.

[84] (*Id.*)

[85] (*Id.*)

[86] (*Id.*)

[87] (*Id.* at 3-5.)

[88] (*Id.* at 5-11 (discussing *Altria Grp., Inc. v. Good*, 555 U.S. 70 (2008); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005); *Cippollone v. Liggett Grp., Inc.*, 505 U.S. 504 (1992).)

specialized packing which would have enhanced the safe use of the drug.[89] Plaintiffs also cite to *Medtronic v. Lohr*, 518 U.S. 470 (1996), and argue that their negligence claims against the Generic Defendants remain valid after *Mensing* because the Generic Defendants failed to update their labels as required by the FDA's regulations and did not otherwise inform the medical community of metoclopramide's known risks.[90]

Plaintiffs also rely on the learned intermediary doctrine to support the validity of their failure to communicate theory.[91] They argue that because this medical malpractice defense requires drug manufacturers to adequately communicate warnings to a physician, Tennessee law recognizes a cause of action for failure to communicate warnings not subject to *Mensing*'s impossibility preemption.[92] Plaintiffs also cite to the TPLA's definition section and argue that they have stated a claim against the Generic Defendants due to metoclopramide's unreasonably dangerous nature and condition.[93]

In reply, the Generic Defendants cite to supplemental briefing in *Smith* in which the plaintiffs argued that *Mensing* was a narrow decision for reasons similar to those raised by Plaintiffs here; the Generic Defendants point out that *Smith* rejected those arguments.[94] They also distinguish the three main Supreme Court cases upon which Plaintiffs rely: because *Altria*,

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89 (*Id.* at 12-14.)

90 (*Id.* at 14.)

91 (*Id.* at 15-19.)

92 (*Id.* at 16-17.)

93 (*Id.* at 18-19.)

94 (Generic Defs.' Reply, D.E. # 192, at 3-4.)

Bates, and *Cippollone* are express preemption cases, their analysis is inherently distinct from *Mensing*'s impossibility preemption analysis.[95] Furthermore, they return to their initial argument: all of Plaintiffs' claims are failure to warn claims masquerading as other theories. Plaintiffs even candidly admit that "'their failure to warn causes of action can be referred to as failure to communicate.'"[96] Finally, the Generic Defendants list thirteen federal and state cases applying *Mensing* to failure to warn claims and aver that *Mensing* controls this case and mandates dismissal of all claims against them.[97]

The Court has thoroughly reviewed Plaintiffs' Amended Complaint, and the Court finds that Plaintiffs' claims are essentially failure to warn claims attempting to masquerade as other non-preempted causes of action. As in *Fulgenzi*, "this case comes down to the warning." The Amended Complaint is replete with references to the Generic Defendants' failure to warn of metoclopramide's disturbing and alarming side effects: "[all] Defendants distributed, marketed, promoted, and/or sold an unreasonably dangerous and defective product . . . without adequate warnings or other clinically relevant information and data to consumers . . . [;]"[98] the "Generic Defendants failed to effectively and adequately communicate the warnings in the label and changes to the warnings of the approved label to physicians and patients[;]"[99] when metoclopramide left the Generic Defendants' hands, it "was unreasonably dangerous to the

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95 (*Id.* at 5-7.)

96 (*Id.* at 4-5 (quoting Pls.' Resp., D.E. # 183, at 21).)

97 (*Id.* at 10-13.)

98 (Am. Compl. ¶ 61.)

99 (*Id.* ¶ 64d.)

extent beyond that which would reasonably be contemplated by Plaintiffs or their physicians[;]"[100] the Generic Defendants "failed to use ordinary care in design, testing, and manufacturing [metoclopramide] which would be reasonably safe to use without appropriate labeling, marketing, and/or the provision of adequate information to consumers or doctors [and] failed to use ordinary care in marketing, labeling, and communicating adequate warnings[;]"[101] the Generic Defendants willfully and fraudulently misrepresented to physicians the "safety, efficacy, and risk/benefit ratio" of metoclopramide;[102] the metoclopramide taken by Plaintiffs did not "conform[] to the properties described in the label [and were not] safe for their intended uses, including long term metoclopramide therapy;"[103] and all Defendants "acted with a common purpose to intentionally and/or fraudulently withhold information from the medical community and physicians regarding the safety of . . . metoclopramide."[104] Accordingly, in addition to the individualized holdings below, the Court finds that Plaintiffs' Amended Complaint cannot escape *Mensing*'s reach. At bottom, regardless of their packaging, Plaintiffs' claims against the Generic Defendants "relate to the sufficiency of the [metoclopramide] warnings." Therefore, all of Plaintiffs' claims are subject to preemption as discussed by *Mensing* and as recognized by *Smith*, *Fulgenzi*, and *Darvocet MDL*. As Justice Sotomayor recognized, the Court's ruling effectively precludes recovery against the Generic Defendants for their failure to warn Plaintiffs

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100 (*Id.* ¶ 74a.)

101 (*Id.* ¶ 87a-b.)

102 (*Id.* ¶ 99.)

103 (*Id.* ¶ 123.)

104 (*Id.* ¶ 153.)

of metoclopramide's terrible side effects.[105] The majority implied as much, nothing that "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre."[106] But current law mandates such a result; the wisdom of such an outcome is thus left to the Tennessee General Assembly and Congress to decide. The Generic Defendants' Motion to Dismiss these claims is **GRANTED**.

None of Plaintiffs' arguments persuade the Court otherwise. Plaintiffs' reliance on express preemption cases is not persuasive; express preemption differs from implied preemption,[107] of which *Mensing*'s impossibility preemption is a subset, and in any case, *Mensing* cited implied preemption cases rather than express preemption cases during its preemption discussion.[108] Additionally, Tennessee law is sufficiently similar to that of Minnesota and Louisiana to apply *Mensing* to this case, and contrary to Plaintiffs' assertions, Tennessee law effectively requires a manufacturer to alter its label if it wishes to avoid tort liability. Indeed, prescription drug manufacturers must market and distribute their products while minimizing the risk of danger; adequate warnings and proper instructions reduce this risk. Thus, if a manufacturer distributes a drug without adequate warnings, it exposes itself to liability under the TPLA. To avoid that liability, the manufacturer would have to alter its label to strengthen its warning—exactly the situation presented in *Mensing* and the reason behind the

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[105] *Mensing*, 131 S. Ct. at 2592-93 (Sotomayor, J., dissenting).

[106] *Id.* at 2582 (quoting *Cuomo v. Clearing House Ass'n, L.L.C.*, 129 S. Ct. 2710, 2733 (2009) (Thomas, J., concurring in part and dissenting in part)).

[107] *See, e.g.*, *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287-89 (1995) ("*Cipollone* supports an inference that an express preemption clause forecloses implied preemption; it does not establish a rule.").

[108] *Mensing*, 131 S. Ct. at 2577-81.

Supreme Court's preemption holding: the manufacturer would not be able to strengthen its label and comply with the FDA's sameness requirement. Accordingly, the Court is not persuaded by this argument.

Plaintiffs' assertion that the Generic Defendants could have sent Dear Doctor letters or other communications to physicians or patients is also preempted; the FDCA classifies Dear Doctor letters as a form of labeling subject to the same "sameness" requirement as other labels. Thus, these claims are preempted by *Mensing* and are without merit. Furthermore, the learned intermediary doctrine does not save Plaintiffs' failure to warn claims. Physicians raise the learned intermediary defense in medical malpractice actions; it is not an independent cause of action.[109] And even if Plaintiffs could sue under it, their claims would still sound in the failure to warn realm and would be preempted by *Mensing*. Finally, Plaintiffs' assertion that metoclopramide is unreasonably dangerous on its own is a failure to warn claim in disguise: metoclopramide is only unreasonably dangerous if it is taken for more than twelve weeks or given to children. These unreasonably dangerous conditions could have been easily prevented by warning physicians not to prescribe metoclopramide in those ways. Thus, Plaintiffs' claims resting on an unreasonably dangerous theory are also failure to warn claims and are preempted by *Mensing*. The Generic Defendants' Motion to Dismiss is **GRANTED** in this regard.

Failure to Conform Claims

In their Motion, the Generic Defendants argue that Plaintiffs' failure to conform claims, in which they allege that the Generic Defendants were negligent because they failed to apply

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[109] *See, e.g., Smith v. Pfizer, Inc.*, 688 F. Supp. 2d 735, 745-47 (M.D. Tenn. 2010) (discussing the learned intermediary doctrine as a defense rather than a cause of action).

changes made to Reglan's label to their metoclopramide labels, are impermissible attempts to enforce the FDA's regulations, which is prohibited by *Buckman*.[110] Notwithstanding *Buckman*, the Generic Defendants point out that at *Mensing*'s oral argument, the Supreme Court did not address the generic manufacturers' possible failure to implement changes to their labels.[111] Additionally, when presented with the argument in an en banc petition, the *Smith* court denied rehearing.[112] Thus, the Generic Defendants argue that Plaintiffs' failure to conform claims are preempted or otherwise unavailing.

In response, Plaintiffs argue that their failure to warn cause of action "can be referred to as failure to communicate the information known to the Generic Defendants in ways other than through labeling."[113] They assert that the Generic Defendants failed to communicate or incorporate the actual FDA approved label for Reglan into their labels for metoclopramide and that "this failure to warn (other than through FDA approved labeling) does not run afoul of 'impossibility preemption' as explained by" *Mensing*.[114]

As before, the Court is not persuaded by Plaintiffs' attempt to paint their failure to conform claim as anything other than what it is. Plaintiffs' assorted failure to conform allegations impermissibly attempt to enforce FDA regulations in violation of *Buckman*. Therefore, all of Plaintiffs' claims based on the Generic Defendants' failure to conform their

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110 (Generic Defs.' Mot., D.E. # 173-1, at 13.)

111 (*Id.* at 14.)

112 (*Id.* at 14-15.)

113 (Pls.' Resp., D.E. # 183, at 21.)

114 (*Id.*)

labels to those of the Brand Name Defendants are preempted or otherwise unavailing. Therefore, the Generic Defendants' Motion to Dismiss these claims is **GRANTED**.

Failure to Remove Products from the Market

In their Motion, the Generic Defendants argue that Tennessee law does not impose a duty to recall products or to cease selling products approved by the FDA.[115] The Generic Defendants also cite to several cases holding that they had no independent duty to withdraw their products from the market.[116] Thus, the Generic Defendants return to *Mensing* and argue that Plaintiffs' statutory and common law claims are preempted.[117] The Court agrees: all of Plaintiffs' assorted claims raising allegations that the Generic Defendants failed to remove metoclopramide from the market are invalid due to *Mensing* and *Smith*'s rejection of this theory. Therefore, the Generic Defendants' Motion to Dismiss these claims is **GRANTED**.

Unjust Enrichment and Civil Conspiracy Claims

In their Motion, the Generic Defendants argue that the facts in Plaintiffs' Amended Complaint set out only failure to warn claims; they do not provide factual support for their unjust enrichment or civil conspiracy claims as required by *Twombly* and *Iqbal*.[118] Accordingly, the Generic Defendants move for dismissal of these claims. The Court has already dismissed Plaintiffs' unjust enrichment claim as discussed above. In response to the Generic Defendants' arguments regarding civil conspiracy, Plaintiffs rely on *Cippollone* and argue that *Mensing*'s

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115 (Generic Defs.' Mot., D.E. # 173-1, at 17.)

116 (*Id.* at 17-18.)

117 (*Id.* at 18.)

118 (*Id.*)

preemption would not apply to their civil conspiracy claim arising from the Generic Defendants' "statements, advertising, or claims made outside of the product labeling as part of the conspiracy between name brand and generic manufacturers."[119]

Plaintiffs have misplaced their reliance on *Cippollone*: an express preemption case will not save their civil conspiracy claim from preemption under *Mensing*'s impossibility preemption analysis. The Court agrees with the Generic Defendants: they have not provided factual allegations to support their civil conspiracy claim, and even if they had, their civil conspiracy claim sounds in failure to warn, which is preempted by *Mensing*. Therefore, the Generic Defendants' Motion to Dismiss this claim is **GRANTED**.

Fraud, Intentional Misrepresentation, and Negligent Misrepresentation

In their Response, Plaintiffs argue that they alleged each of the required elements of these three causes of action, and the Generic Defendants had "avenues other than changes to the FDA approved labeling by which [they] could have conveyed the risks of this unreasonably dangerous product to Plaintiffs and/or their physicians, including . . . Dear Doctor . . . letters[,] not to strengthen the FDA mandated labeling, but to convey that labeling."[120] Thus, Plaintiffs allege that they have successfully stated these claims. In their Reply, the Generic Defendants reassert their arguments that Dear Doctor letters and other such physician- or patient-direct communications are preempted: they point out that the *Smith* plaintiffs' supplemental briefing addressed such a theory, and the *Smith* court rejected it.[121] They also reiterate their reliance on

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[119] (Pls.' Resp., D.E. # 183, at 23-24.)

[120] (*Id.* at 20.)

[121] (Generic Defs.' Reply, D.E. # 192, at 7.)

FDA regulations classifying Dear Doctor letters as "labeling" subject to the sameness requirement—one of the bases for *Mensing*'s preemption finding.[122]

Once again, the Court agrees with the Generic Defendants. Plaintiffs' arguments are untenable in light of *Smith* and *Mensing*. Dear Doctor letters are labeling, and *Mensing* preempts and any claim related to Dear Doctor letters in addition to or different from that sent by the Brand Name Defendants. Moreover, *Smith*'s brief analysis of *Mensing* reveals the broad sweep of *Mensing*'s holding and *Smith*'s failure to grant the plaintiffs relief in the face of comparable arguments requires the Court to rule similarly. The Court declines Plaintiffs' implicit invitation to overrule the Sixth Circuit or the Supreme Court. Therefore, the Generic Defendants' Motion to Dismiss these claims is **GRANTED**.

Negligence

In their Response, Plaintiffs argue that they have successfully stated a claim for negligence other than as a failure to supplement or revise the FDA approved label.[123] They point out that "whether [the Generic] Defendants were negligent in selling or in failing to use reasonable care to test or use reasonable care in marketing and promotion of their unreasonably dangerous product are questions of fact that do not involve reference to the product labeling."[124] Plaintiffs argue that they have stated a negligence claim under the TPLA's dual tests for

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122 (*Id.* at 8-10.)

123 (Pls.' Resp., D.E. # 183, at 20-21.)

124 (*Id.* at 21.)

defective products—the consumer expectation test and the prudent manufacturer test—because neither of these tests involves FDA-approved labeling.[125]

The consumer expectation test "can only be applied to products about which an ordinary consumer would have knowledge;"[126] because metoclopramide is not such a product, Plaintiffs are limited to the prudent manufacturer test. But even under this test, Plaintiffs' claims all sound in failure to warn rather than as any other claim. Accordingly, they are preempted by *Mensing*. Therefore, the Generic Defendants' Motion to Dismiss this claim is **GRANTED**.

Strict Liability

In their Response, Plaintiffs recite the elements of a strict liability action under the TPLA and aver that their strict liability claims cannot be dismissed because they have pled that the Generic Defendants sold metoclopramide in an unreasonably dangerous condition, that Plaintiffs received medication in that condition, and that the metoclopramide's unreasonably dangerous condition caused their injures.[127] Thus, they argue that "nothing about this strict liability claim relates to the FDA approved labeling" and that *Mensing* does not apply to their strict liability claim.[128] But the Court already addressed this argument and found that metoclopramide's unreasonably dangerous condition arose only if patients took it for longer than twelve weeks. Accordingly, Plaintiffs' strict liability claim is also a failure to warn claim in disguise, and it is

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125 (*Id.*)

126 *Ray by Holman v. BIC Corp.*, 925 S.W.2d 527, 531 (Tenn. 1996).

127 (Pls.' Resp., D.E. # 183, at 21.)

128 (*Id.* at 21-22.)

preempted by *Mensing*. Therefore, the Generic Defendants' Motion to dismiss these claims is **GRANTED**.

Breach of Warranty and Merchantability

In their Response, Plaintiffs recite Tennessee's law regarding breach of express and implied warranty, and they state that the "have sufficiently pled breach of express and implied warranty which may be demonstrated without requiring that the [Generic] Defendants' labeling that exceeds the FDA approved labeling [sic]," but they do not state how their Amended Complaint reflects such a claim.[129] Regardless, the Court finds that these breach of warranty claims relate to the sufficiency of the metoclopramide warnings, and *Mensing* preempts them. Therefore, the Generic Defendants' Motion to dismiss these claims is **GRANTED**.

Derivative Claims

Plaintiffs' Amended Complaint also contains claims for wrongful death, survival action, and punitive damages.[130] In their Response, Plaintiffs argue that their punitive damages claim does not involve labeling and that *Mensing* "clearly does not mandate dismissal of the punitive damage claims as to the Generic Manufacturers."[131] These claims derive from other more substantive claims in Plaintiffs' Amended Complaint. The Court has dismissed all of Plaintiffs' other claims against the Generic Defendants. To the extent that Plaintiffs' wrongful death, survival action, and punitive damages claims derive from Plaintiffs' claims against the Generic Defendants, these derivative claims are also **DISMISSED**.

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129 (Pls.' Resp., D.E. # 183, at 23.)

130 (Am. Compl., D.E. # 171, at 59-64.)

131 (Pls.' Resp., D.E. # 183, at 24.)

CONCLUSION

For the foregoing reasons, the Generic Defendants' Motion is **GRANTED**. All claims by those Plaintiffs who took Reglan and those who took metoclopramide against the Generic Defendants are hereby **DISMISSED**. Plaintiffs' claims against the Brand Name Defendants survive this ruling regardless of whether Plaintiffs took Reglan or metoclopramide.

IT IS SO ORDERED.

s/ S. Thomas Anderson
S. THOMAS ANDERSON
UNITED STATES DISTRICT JUDGE

Date: August 8, 2012.